CENTRE FOR SOCIETY AND POLICY

Emerging preferences in intellectual property - Lessons from the COVID-19 crisis[1]

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The coronavirus pandemic has spurred some unusual initiatives in the intellectual property (IP) domain. The open COVID pledge[i] by several companies and universities in order to galvanize the development of treatment and cures for COVID-19, ensures everyone has access to the technology needed to mass-produce masks, ventilators, and testing kits. Numerous recent legislative developments around the world are laying the foundation for compulsory licensing of COVID-19 related patents. The initiatives aim to improve accessibility to innovations that could play a strong part in dealing with a critical global issue. However, these global cooperation-based initiatives open the IP domain to several critical discussions.

This article maps the IP events evolving from the current pandemic health crisis and carves out new archetypes highlighting the need for similar structures for the current and emerging economic, environmental, and social uncertainties. We aim to explore aspects that encourage equitable access and reasonable affordability for the world population. The article forms a part of the series to understand the various shapes IP can take in the near future.

What new structures do we see in recent times?

Global cooperation, collaboration, and partnership

The outbreak of COVID-19 spurred several innovations[ii] in the area of health including medical care, health technologies, and health systems. Dozens of projects have come forward to develop a vaccine for the 2019-nCoV infection. We see collaboration

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between smaller manufacturers and large firms like US biotech Inovio Pharmaceuticals Inc. with German Richter-Helm Biologics; collaboration between leading giants such as French Sanofi SA and British GlaxoSmithKline Plc for accelerating the manufacturing efforts; and collaboration between private entities and universities such as the Pune-based Serum Institute of India and University of Oxford to develop the ChAdOx1 nCoV-19 vaccine.

These innovations are getting shared across national boundaries, initiating spontaneous partnerships, and widening the doors of international collaborations between nations, companies, institutions, and universities. Sharing forms include free licenses to patents, copyrights, and certain other property rights to anyone developing technologies for the diagnosis, prevention, or treatment of COVID-19. The development of COVID-19 diagnostic kits merely in a matter of weeks after the outbreak[4], uniformity in guidelines globally to contain the propagation of the virus, international cooperation in sharing medicine, vaccine development, and informatics on casualties are some examples of sustainable global cooperation we witness in recent times.

The case of vaccine development at the University of Oxford demonstrates the ease of public-private partnership as well. For example, the clinical trials at the University of Oxford are being funded by the UK Government and the 7 manufacturing partners in this project are private entities, three in Britain, two in Europe, one in India, and one in China. The projections predict this vaccine might surface global markets within six months, which otherwise, takes at least a year.

Compulsory licensing

Compulsory licensing is a mechanism whereby governments can authorize a third-party to make, use or sell a particular product or use a particular process without the permission of the patent owner[iii]. Governments can employ compulsory licensing during national emergencies, and the COVID-19 pandemic outbreak is being seen as such emergency. Recently, Israel issued[iv] a compulsory license for Kaletra medicine of AbbVie to the Indian drug maker Hetero for making the generic version of the drug at affordable prices and adequate quantities. Other countries are exploring similar ways as well. For example, Chile's Lower House of Parliament[v] and Ecuador's National Assembly[vi] have passed resolutions for COVID-19 products; Canada has passed the COVID-19 Emergency Response Act[vii]; Germany has enacted an Infectious Diseases

[4] Rebecca Tan, COVID-19 Diagnostics Explained, Asian Scientist Magazine, https://www.asianscientist.com/2020/04/features/covid-19-diagnostics-explained, April 08th, 2020.

Act assuring powers with respect to compulsory licenses[viii]; and France has enacted a new emergency law 2020-290[ix].

Patent pools, pledges, and fair uses

World leaders have come together to develop plans for the accessibility of COVID-19 IP rights. European Union is contemplating buying COVID-19 related rights and establish a publicly-owned patent pool or fund. The latter would constitute a significant development in the IP marketplace and an unprecedented government effort to ensure patents do not obstruct the fight against the pandemic. The leading Medicine Patent Pool has also shown interest[x] in lending their model and expertise which were previously involved in voluntary licensing mechanisms in low- and middle- income countries.

The World Health Organization is exploring a voluntary pool of IP rights[xi] for new technologies, test data, and other sharable information for developing drugs, vaccines, and diagnostics. The Costa Rican government officials were the first to propose this amid mounting concerns on some COVID-19 medical products being accessible for poorer populations. Establishment of a voluntary mechanism under the auspices of the WHO opens a pathway to attract numerous governments, as well as industry, universities and non-profit organizations[xii].

Patent sharing as philanthropy/social commitment

Given the severity of the pandemic, several rights holders have already pledged not to exclude others from using their inventions. Private companies are committing to not use IP as a tool to gain a competitive advantage in the short term at the expense of public health. For example, AbbVie has announced non-enforcement of their patents on Kaletra (usually used to treat HIV, but thought potentially to treat COVID-19) and Gilead has sought to rescind the seven-year orphan drug exclusivity period for the repurposed Remdesivir[xiii]. Further, Indian vaccine manufacturer, Serum Institute of India, has announced non-filing of patent rights for the COVID related research and manufacturing[xiv].

What does this mean for IP in the near future?

COVID-19 has opened doors for exploring alternate ways for the industry to (and must) operate. As Jamie Love, Head of Knowledge Ecology International says, "This is not

an attack on intellectual property. It's the right magnitude of the response given the magnitude of the problem"[xv]. Following from Jamie Love, a leading discussion focuses on exploring *newer, more equitable, and commercially reasonable, license terms.* The purpose of creating IP was to allocate rights with the understanding that innovation should be made public, with a limited monopoly of the owners. Over the years this has got misused to fight battles of supremacy and blocking of access. A glaring example being the long fight by US pharmaceutical firms to limit the low-cost generic production of antiretroviral medicines used to treat HIV. In South Africa, where AIDS deaths had reached 100,000 and were growing, the US pharmaceutical firms were pressuring South Africa to stop the production of generics meant to save the citizens' lives. Even with millions of lives at stake, public health has continued to take a backseat to intellectual property. The coronavirus pandemic may finally change those calculations.

Government as a facilitator rather than just a regulator

The government's role as a facilitator emerges steadfast, as an intermediary while setting of fair-trade terms or provide arbitration in the wake of dysfunctionalities of patent pools or cross-licensing arrangements. This might bring more transparency in the structure and hopefully create more equitable access. These can be extended to not just health but agriculture technologies, environmental technologies, educational aids and material for good mental health, and public space management.

Patents sharing under specific conditions of public good

Patent sharing should be allowed/facilitated in instances where companies/people need to combine several patents, or need the freedom to operate in a particular jurisdiction for higher capacity and lower prices in order to directly benefit global populations. For example, the patent negotiation between China's Wuhan Institute of Virology and Gilead for pricing of their patented drug without enforcing compulsory licensing issuance (use of remdesivir for the treatment of COVID-19) is a case in point. If the patent gets issued for repurposed remdesivir, the Institute and Gilead cannot enforce their respective patents without each other's approval and cross-licensing of patents, unless one of them waives off or surrenders its rights.

In such circumstances, other strategic options should be open to both parties. Some hybrid structures could be as listed below. These options are slightly different from compulsory licensing or voluntary licensing, and similar to when Gilead voluntary licensed hepatitis C drug, Sovaldi in 2015[xvi].

- **Government facilitated voluntary licensing, with negotiated price with the government:** In this option, the government negotiates with the patent owner for lower pricing, rather than evoking compulsory licensing. Negotiating for voluntary licenses at reasonable rates does not impede the rights of a patent owner.

  Governments can take initiatives for technology transfers based on fair, reasonable, and non-discriminatory (FRAND) terms. This will bring harmonised technology and royalty flow as well as better channelling of public products, not just limited to health but also including agriculture technologies, software for better management of public commons like transportation and parks, education and awareness material, and relief services.

- **Active exploration of IP and non-IP incentives:** An example of the pharmaceutical market dynamics of vaccines highlights the necessity of this option. Most of the biopharmaceutical corporations undermine the vaccine business considering its unprofitability[xvii]. Longer efficacy of vaccine stands for smaller demands[xviii]. Case in point being the initial resistance of most firms in being part of vaccine development under the USNIH's R&D program in the initial months of COVID-19 outbreak[xix]. Resolutions to these kinds of difficulties can be met through the pairing of IP and non-IP incentives[xx].

  Amalgamation of IP and non-IP incentive mechanisms might support licensing arrangement between unequal parties. Also, this may actively support IP-intensive essential goods and services having limited market penetration. Transferable/roaming intellectual property rights (TIPR), whereby a company gets awarded additional IP on a product of its choice in exchange for developing a given neglected disease product; fast track accelerated approval (TFT) whereby a company receives more rapid regulatory review for a product of its choice in exchange for developing a neglected disease product (effectively lengthening the period of patent protection for the chosen product); and advance purchase commitments (APCs) provided through a guaranteed purchase fund are some non-IP incentive options[xxi].

- **Public-private partnerships:** Public-private partnerships can be a good tool to beat several R&D challenges including long term funding, capacity building, and legal compliance. The COVID-19 crisis shows most of the research being conducted recently involving a range of players through the vehicle of public-

private partnerships which, on the basis of funding from philanthropic sources, are able to harness the skills of different organisations at different stages of the R&D process.

Policymakers can take several innovative steps to encourage innovation in areas of public commons, like increase in research funding in areas directly addressing development, move pro-poor technologies quickly through the regulation process, and funding support and joint ownership for innovations with increased likelihood of mitigating some of the global ills.

Public private partnerships can be an effective incentivising tool post-COVID 19 for industrial growth as well, considering the economic slowdown and the impact on the industries. Assistance in finding appropriate research or manufacturing partner, identification of freedom to operate beyond laboratory conditions, and framing of terms and conditions adopted for technology transfers can be accelerated through national-level guidance by respective governing bodies.

Conclusion

Should this pandemic be an exception or the norm? While the debate goes on, some call for action is imperative and needs execution. International agencies like WHO, UN, and UNICEF have to start discussions with the various government on policy and legislative measures to ensure patents and other intellectual property do not erect barriers to access to global common goods like food security, climate change, poverty alleviation, and infant health. Further, measures to facilitate local manufacturing or import of essential supplies for global social good may require policy and legal realignment of international intellectual property and trade rules as well.

BIBLIOGRAPHY

[i] https://opencovidpledge.org/

[ii] https://www.genengnews.com/virology/coronavirus/catching-up-to-coronavirus-top-60-treatments-in-development/

[iii] This mechanism was pronounced by the WTO Ministerial Conference, 2001 Doha Declaration under the TRIPS agreement.

[iv] https://www.keionline.org/wp-content/uploads/A-Permit-to-the-State-to-Exploit-an-Invention-Pursuant-to-Chapter-Six-Article-Three-of-the-Patents-Law-5727-1967.pdf

[v] https://www.keionline.org/wp-content/uploads/resolucioncoronavirus.pdf; and https://www.keionline.org/chilean-covid-resolution

[vi] https://www.keionline.org/wp-content/uploads/ES-Ecuador-CL-resolution.pdf

[vii] https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/royal-assent

[viii] https://www.gesetze-im-internet.de/ifsg/index.html

[ix] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000041746313&categorieLien=id

[x] https://medicinespatentpool.org/mpp-media-post/the-medicines-patent-pool-stands-ready-to-offer-support-as-needed-in-access-to-treatment-for-the-coronavirus/

[xi] https://www.statnews.com/pharmalot/2020/04/06/covid19-coronavirus-patents-voluntary-pool-world-health/

[xii] https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/

[xiii] https://www.livemint.com/news/india/government-may-not-press-gilead-on-potential-covid-19-drug-11588012215502.html

[xiv] https://www.hindustantimes.com/india-news/indian-firm-ready-to-beginproducing-possible-vaccine/story-P6muJdn2p2mtzna7jh40SI.html

[xv] https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/

[xvi] https://www.livemint.com/news/india/government-may-not-press-gilead-on-potential-covid-19-drug-11588012215502.html

[xvii] https://scholarship.law.slu.edu/faculty/331/

[xviii] Patricia M. D., Nuno Sousa Pereira, and Sapna S. Tejwani. 2005. Vaccine Supply: A Cross-National Perspective, Health Affairs. 24(3), 706-707. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.3.706

[xix] https://www.statnews.com/2020/02/11/major-drug-makers-havent-stepped-up-to-manufacture-coronavirus-vaccine-top-u-s-health-official-says/

[xx] https://scholarship.law.slu.edu/faculty/331/

[xxi] https://www.who.int/intellectualproperty/studies/A.Towse.pdf?ua=1